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#### DETAILED ACTION

#### Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-26, drawn to an article of manufacture.

Group II, claim(s) 27 and 28, drawn to a dispenser, adapted to receive the article of manufacture.

Group III, claim(s) 29-52, drawn to a method of forming a hydrogel.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 29, at least, is anticipated by or obvious over US 6231605. Consequently, the special technical feature which links the claims, the hydrogel component, does not provide a contribution to the prior art, so unity of invention is lacking.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Group I is elected:

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There are three genii and species election requirements as follows:

### Genus A:

(a) wherein the first chambers contain both the gellant and the polymer solution.

(b) wherein the first chambers contain the polymer solution and the gellant is in a second chamber.

# Genus B:

- (a) wherein the gellant is active went contacted with the polymer solution.
- (b) wherein the gellant is inactive went contacted with the polymer solution.

## Genus C:

- (a) wherein the gellant is selected from the group in claim
- 17.
- (b) wherein the gellant is selected from the group in claim
- 18.
- (c) wherein the gellant is an alkali salt.
- (d) wherein the gellant is selected from the group in claim
- 22.
- (e) wherein the gellant is a polyether.

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If Group III is elected:

There are also three separate genii, species and subspecies election requirements as follows:

## Genus A':

- (a) wherein the step of heating the hydrogel is performed by conduction by direct or indirect contact with a heat source.
- (b) wherein the step of heating the hydrogel is performed by absorption by the hydrogel of infrared or microwave radiation.

#### Genus B':

- (a) wherein the space where the hydrogel is formed is a body cavity.
  - (i) further wherein the body cavity is an intervertebral disk.
  - (ii) further wherein the body cavity is an articulated joint.
  - (iii) further wherein the body cavity is a subdermal space.

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(b) wherein the space where the hydrogel is formed is a mold

#### Genus C':

- (a) wherein the walls of the space where the hydrogel is formed are pre-treated by cooling the walls with a cooling probe or by flushing with cold saline.
- (b) wherein the walls of the space where the hydrogel is formed are pre-treated by coating the interior walls with the gellant.

For each genus, if the relevant Group is elected, applicant is required, in reply to this action, to elect a single species (or subspecies) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species (or subspecies), including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: Claim 1 for Group I and Claim 29 for Group III.

The claims are deemed to correspond to the species listed above in the following manner:

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# For Group I

# Genus A:

- (a) Claim 2.
- (b) Claims 3 and 4.

## Genus B:

- (a) Claim 10.
- (b) Claim 11.

# Genus C:

- (a) Claim 17.
- (b) Claim 18.
- (c) Claims 19-21.
- (d) Claim 22.
- (e) Claims 23-25.

# For Group III:

## Genus A':

- (a) Claim 31.
- (b) Claim 32.

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# Genus B':

- (a) Claims 35 and 38-42.
  - (i) Claim 40.
  - (ii) Claim 41.
  - (iii) Claim 42.
- (b) Claim 36.

### Genus C':

- (a) Claim 48.
- (b) Claim 49.

#### 3. REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

# WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- A product and a process specially adapted for the manufacture of said product; or
  - (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

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 A telephone call was made to John Isacson on 6/9/10 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof.

Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case.

Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kelechi C. Egwim whose telephone number is (571) 272-1099. The examiner can normally be reached on M-T (7:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner, Art Unit 1796

KCE